IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

United States of America, Plaintiff, -vs- Shaffer Pharmacy, Inc., et al., Defendants.	Case No. 3:21 CV 22 ORDER DENYING MOTION FOR PRELIMINARY INJUNCTION JUDGE JACK ZOUHARY

The Government filed a Complaint against Defendants Shaffer Pharmacy, Inc. ("Shaffer"), and its two pharmacists Thomas Tadsen and Wilson Bunton (Doc. 1). The Complaint asks for injunctive relief and monetary penalties for alleged violations of the Controlled Substance Act ("CSA"), 21 U.S.C. § 801 et seq. The Government successfully sought a Temporary Restraining Order (Doc. 7) prohibiting Defendants from continuing to sell controlled substances. The Government now seeks a permanent injunction (Doc. 3-1) under CSA Section 843(f). Defendants oppose (Doc. 18).

This Court held a hearing on January 27–29, 2021; heard testimony from Government witnesses Dr. Carl Gainor and DEA Diversion Investigator Meredith Carter; and from both Defendant pharmacists. The parties agreed to a Joint Stipulation of Facts (Doc. 20) and offered a number of exhibits at the hearing.

When a court is called upon to enforce a federal statutory injunction, "its reliance upon the traditional practices of equity must be conditioned by the necessities of the public interest which Congress has sought to protect." *United States v. City of Painesville*, 644 F.2d 1186, 1193 (6th Cir. 1981) (citation omitted). Because the CSA is a Congressional Act to protect the public health, "the

Government only needs to establish that [Defendants] violated the statute and there is some cognizable danger of recurrent violation." *United States v. Scotty's, Inc.*, 173 F. Supp. 3d 549, 553 (E.D. Mich. 2016). *See also United States v. Flu Fighter Corp*, 2009 WL 10668958, at *7 (S.D. Fla. 2009) (citing *Gresham v. Windrush Partners, Ltd.*, 730 F.2d 1417, 1423 (11th Cir. 1984); *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)). However, even if the standard four-factor test for determining the merits of a preliminary injunction were utilized here, the outcome would be the same.

The Government's pharmaceutical expert Dr. Gainor -- after reviewing available records -- found numerous red flags (e.g., high MME dispensing; dangerous drug combinations; prescriptions not justified by diagnosis codes; multiple prescribers; and duration of opioid therapy) surrounding opioid purchases from Defendants for the years 2015–20. He did not find documentation in Defendants' records (RX 30) adequately resolving these "red flags" by determining if there was "a legitimate medical purpose" for the prescriptions, in violation of the CSA (21 C.F.R. § 1306.04).

But problems began for Defendants before this lawsuit. One of its major suppliers, AmerisourceBergen ("ASB"), declined to continue supplying narcotics to Defendants in 2019 (Doc. 22-1), and its new supplier Cardinal Health has put in place some limitations as well. As a result, the number of opioid prescriptions filled by Shaffer has been reduced dramatically (Doc. 3-2 at 12; Doc. 18 at 3). Consequently, current rates of opioid prescriptions filled by Shaffer have dropped to a rate parallel to a typical pharmacy in the area. *Id.* Additionally, evidence prepared for this hearing -- after this case was filed -- based on conversations Defendants Tadsen and Bunton had with long-term patients or their respective doctors -- attempts to explain those opioid prescriptions that were flagged by the Government (Doc. 23-3). These Johnny-come-lately justifications appear to explain many, if

not all, of the red flags cited by the Government. However, corroboration of these accounts will obviously be needed as this case progresses.

Defendants clearly failed to keep adequate contemporaneous records of their resolution of red flags. Tadsen and Bunton each testified that they verbally resolved red flags, relying both on their relationships with doctors, as well as observing and talking with patients with whom they worked closely. While Defendants may have been satisfied, they failed to follow the Ohio Administrative Code ("OAC") which requires pharmacists to maintain documentation of, among other items, "pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug." Ohio Admin. Code 4729-5-18(A)(1)(f). This documentation may be kept in written or electronic form and must be kept for at least one year from the date of the last entry in the patient's profile. *Id.* These Defendants did not appear to do so in all cases; Dr. Gainor found only one example of a red-flag resolution being documented electronically in the RX30 system, out of the twenty patients he reviewed (Doc. 3-4 at 28–29).

Defendants do acknowledge that best practices would require much more by them. In fact, Defendants prepared a written policy that would comply with the OAC -- Exhibit 7 (Doc. 22-7). They did this in 2019 in an attempt to stave off ASB from cutting its supply to Defendants (Doc. 22-1). But, Defendants admitted, when their offer was rejected, they never implemented the written policy which would have satisfied the OAC requirements (Doc. 22-7 at 6). That policy requires Defendants to obtain a treatment plan from physicians before filling suspect prescriptions. *Id*.

The opioid crisis is real and has made abundantly clear the need for caution by both doctors and pharmacists. Pharmacies are a highly regulated industry -- for good reason -- to ensure the safety of their patients. These Defendants suggest they are capable gatekeepers, but the potential consequences are too tragic for Defendants to simply trust their instincts and ignore protocols.

Because suppliers -- including both ASB and Cardinal Health -- have already forced Defendants to reduce the opioid prescriptions, and because it is not clear at this stage that the CSA was violated or that there is a cognizable danger of it being violated going forward, the Motion for Preliminary Injunction (Doc. 3-1) is denied; the TRO (Doc. 7) lifted; and in its place the following is imposed.

Defendants must immediately supplement their recordkeeping, specifically with respect to identifying and documenting sufficient resolutions of "red flags," in addition to fully conforming to their own written policy on handling prescriptions for controlled substances (Doc. 22-7). Adequate documentation demonstrating this compliance must be available for immediate inspection by the Government on a bi-weekly basis going forward until further Order of this Court. Counsel for all parties shall confer and agree on the necessary steps to implement this Order. Any suspected failures by Defendants shall be immediately brought to this Court's attention.

Even assuming, without deciding, that Defendants violated the CSA, given the current reduction in Defendants' opioid business, the danger of recurrent violations has been minimized. And, with the implementation of the best practices and Government oversight, future violations are even further minimized -- if not eliminated. Defendants are now required to address the legitimacy of a prescription in a contemporaneous writing prior to dispensing (Doc. 1 at ¶¶ 26–27) to meet a "legitimate medical purpose."

IT IS SO ORDERED.

s/ *Jack Zouhary*
JACK ZOUHARY
U. S. DISTRICT JUDGE

February 1, 2021